AMENDED IN ASSEMBLY JUNE 20, 2007

AMENDED IN SENATE MAY 21, 2007

AMENDED IN SENATE APRIL 30, 2007

AMENDED IN SENATE APRIL 16, 2007

AMENDED IN SENATE APRIL 9, 2007

# SENATE BILL No. 472

**Introduced by Senator Corbett**

February 21, 2007

An act to add Section 4076.5 to the Business and Professions Code, relating to pharmacy.

LEGISLATIVE COUNSEL'S DIGEST

SB 472, as amended, Corbett. Prescription drugs: labeling ~~requirements and panel.~~ *requirements.*

Existing law, the Pharmacy Law, provides for the licensure and regulation of the practice of pharmacy by the California State Board of Pharmacy in the Department of Consumer Affairs. Existing law prohibits a pharmacist from dispensing a prescription, except in a container that meets certain labeling requirements.

This bill would require the board to ~~convene a prescription drug label panel, with specified membership, for purposes of reviewing and making recommendations on a standard format for the labeling of prescription drug containers dispensed in the state that is affordable for pharmacies. The bill would require the panel to make a recommendation for a standardized prescription drug container label to the board on or before October 31, 2008, would require the board to promulgate regulations establishing requirements for a mandatory standardized label for~~

~~prescription drug containers within 90 days of receiving the panel's recommendation, and would require specified pharmacies in the state to begin using the standardized labels within 90 days of the effective date of the regulations. The bill would require that pharmacy consultations by a telephonic translation service be available to patients with limited English language proficiency, and that pharmacies be authorized to issue translated prescription drug labels, as specified~~ *promulgate regulations that require, on or before January 1, 2011, a standardized, patient-centered, prescription drug label on all prescription medication dispensed to patients in California. The bill would require the board to hold special public meetings statewide in order to seek information from certain groups, and would require the board to consider specified factors in developing the label requirements. The bill would require the board to report to the Legislature on or before January 1, 2010, on its progress at the time of the report, and to report to the Legislature on or before January 1, 2013, on the status of implementation of the requirements*.

Because a knowing violation of the Pharmacy Law constitutes a crime, and because the above-described provisions would impose additional duties under that law, this bill would impose a state-mandated local program.

The California Constitution requires the state to reimburse local agencies and school districts for certain costs mandated by the state. Statutory provisions establish procedures for making that reimbursement.

This bill would provide that no reimbursement is required by this act for a specified reason.

Vote: majority. Appropriation: no. Fiscal committee: yes. State-mandated local program: yes.

*The people of the State of California do enact as follows:*

SECTION 1. This act shall be known and may be cited as the California Patient Medication Safety Act.

SEC. 2. The Legislature hereby finds and declares all of the following:

(a) Health care costs and spending in California are rising dramatically and are expected to continue to increase.

(b) In California, prescription drug spending totaled over $188 billion in 2004, a $14 billion dollar per year spending increase from 1984.

(c) Prescription drug cost continues to be among the most significant cost factors in California's overall spending on health care.

(d) According to the Institution of Medicine of the National Academies, medication errors are among the most common medical errors, harming at least 1.5 million people every year.

(e) Up to one-half of all medications are taken incorrectly or mixed with other medications that cause dangerous reactions that can lead to injury and death.

(f) Approximately 46 percent of American adults cannot understand the label on their prescription medications.

(g) Ninety percent of Medicare patients take medications for chronic conditions and nearly one-half of them take five or more different medications.

(h) Nearly six out of 10 adults in the United States have taken prescription medications incorrectly.

(i) The people of California recognize the importance of reducing medication-related errors and increasing health care literacy regarding prescription drugs and prescription container labeling, which can increase consumer protection and improve the health, safety, and well-being of consumers.

(j) The Legislature affirms the importance of identifying deficiencies in, and opportunities for improving, patient medication safety systems in order to identify and encourage the adoption of structural safeguards related to prescription drug container labels.

(k) It is the intent of the Legislature to adopt a standardized prescription drug label that will be designed by ~~a panel appointed to work with the California State Board of Pharmacy and that will be implemented in all California outpatient community and mail service pharmacies providing prescriptions to patients.~~ *the California State Board of Pharmacy for use on any prescription drug dispensed to a patient in California.*

SEC. 3. Section 4076.5 is added to the Business and Professions Code, to read:

~~4076.5. (a) The board, in consultation with professionals in the field, shall convene a prescription drug label panel to review and make recommendations regarding the standardization of prescription drug labels. The panel shall work with the board.~~

~~(b) The board shall delegate board members to work with the panel as it sees fit, and shall staff the panel. Members of the panel~~

~~shall include equal membership among groups representing consumers, such as seniors, and groups representing those with special issues regarding language and cultural competency in the use of prescription drugs, as well as pharmacy and medical professionals. The panel may include, but is not limited to, representatives of all of the following:~~

~~(1) Health plans or their representative association.~~

~~(2) Pharmacy representatives.~~

~~(3) Health care providers or their representative association.~~

~~(4) Faculty representatives from a school of pharmacy.~~

~~(5) Associations related to research, manufacturers, or distributors of pharmaceutical drugs.~~

~~(6) Medical associations.~~

~~(7) Consumer groups, such as senior citizens groups.~~

~~(8) Health advocacy groups.~~

~~(9) The board.~~

~~(10) Language accessibility experts.~~

~~(c) The panel may secure private contributions to fund its responsibilities pursuant to this section.~~

~~(d) The panel's review shall include a study and recommendations of best practices for prescription drug labels, including all of the following topics:~~

~~(1) Medical literacy research that points to increased understandability of labels.~~

~~(2) Improved directions for use.~~

~~(3) Improved font types and sizes.~~

~~(4) Placement of information that is patient centered.~~

~~(5) Standards for implementation by pharmacies, including both of the following:~~

~~(A) Technology requirements to implement the standards.~~

~~(B) Affordability to pharmacies of implementing the standards. The panel shall ensure that its recommendation for implementation of a standardized label is affordable for pharmacies.~~

~~(e) On the recommendation of the panel, the board shall, by regulation, adopt a standardized label for prescription drug containers. The label shall be developed so that it meets all of the following requirements:~~

~~(1) It is understandable for prescription drug users.~~

~~(2) It describes the contents of the container so that prescription drug users with low medical literacy levels can understand it.~~

~~(3) It displays necessary information about properly taking the container's contents so that prescription drug users with low medical literacy levels can understand it.~~

~~(4) It displays mandated warnings about the container's contents so that prescription drug users with low medical literacy levels can understand it.~~

~~(5) Implementation of the standardized label is affordable for pharmacies.~~

~~(f) Pharmacy consultations by a telephonic translation service shall be available to patients with limited English language proficiency. A pharmacy shall be permitted to issue translated labels for prescriptions, provided that those labels are found to be safe and reliable.~~

~~(g) (1) The panel shall be established and begin meeting as soon as possible after January 1, 2008.~~

~~(2) The panel shall make a recommendation for a standardized label to the board on or before October 31, 2008.~~

~~(3) Within 90 days of receiving the panel's recommendation, the board shall promulgate regulations to establish requirements for a standardized label for prescription drug containers, pursuant to subdivision (e), which shall be required to be used by all California outpatient community and mail service pharmacies providing prescriptions to patients.~~

~~(4) Within 90 days of the effective date of the adopted regulations, each pharmacy described in paragraph (3) shall begin using the standardized labels for prescription drug containers.~~

*4076.5. (a) The board shall promulgate regulations that require, on or before January 1, 2011, a standardized, patient-centered, prescription drug label on all prescription medicine dispensed to patients in California.*

*(b) To ensure maximum public comment, the board shall hold public meetings statewide that are separate from its normally scheduled hearings in order to seek information from groups representing consumers, seniors, pharmacists or the practice of pharmacy, other health care professionals, and other interested parties.*

*(c) When developing the requirements for prescription drug labels, the board shall consider all of the following factors:*

*(1) Medical literacy research that points to increased understandability of labels.*

*(2) Improved directions for use.*

*(3) Improved font types and sizes.*

*(4) Placement of information that is patient-centered.*

*(5) The needs of those patients with limited English proficiency.*

*(6) The needs of seniors.*

*(7) Technology requirements necessary to implement the standards.*

*(d) (1) On or before January 1, 2010, the board shall report to the Legislature on its progress under this section as of the time of the report.*

*(2) On or before January 1, 2013, the board shall report to the Legislature the status of implementation of the prescription drug label requirements adopted pursuant to this section.*

SEC. 4. No reimbursement is required by this act pursuant to Section 6 of Article XIII B of the California Constitution because the only costs that may be incurred by a local agency or school district will be incurred because this act creates a new crime or infraction, eliminates a crime or infraction, or changes the penalty for a crime or infraction, within the meaning of Section 17556 of the Government Code, or changes the definition of a crime within the meaning of Section 6 of Article XIII B of the California Constitution.

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